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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,641	09/29/2003	Jong Kil	A03P1068	4692
36802 7590 02/27/2007 PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER SMITH, TERRI L	
			ART UNIT	PAPER NUMBER
			3762	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/674,641

Applicant(s)

KIL ET AL.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

1. Applicant's arguments filed on 31 January 2007 have been fully considered but they are not persuasive. Contrary to Applicant's argument in the last paragraph on page 7 of 8 of the **REMARKS**, Examiner cited in the Office Action mailed on 02 November 2006, that Struble does disclose and suggest a processor operative to evaluate frequencies of left and right atrial signals and, if one of the left and right signals has a higher frequency, the processor determines the atrium with the higher frequency to be the source of atrial flutter as recited in claims 1 and 12 of the present invention, at column 15, lines 49–51 where Struble teaches that the frequency of the sVT can be determined through the collection of timing data (Examiner interprets this teaching as evaluating frequencies). And, as also cited in said Office Action, where Examiner emphasized that the atrial arrhythmias are done in a similar fashion as those of the sVT at column 15, lines 56–58 (emphasis on in a similar fashion), and column 16, lines 1–3 (It is the Examiner's position that the similar fashion is the atrial arrhythmias being evaluated using frequencies also). The claim does not state how the frequencies are evaluated. Therefore, it is also the Examiner's position that the percentages as taught by Struble **also** represent the claimed limitations of evaluating a frequency **and** a higher frequency where a percentage of 60% is higher than a percentage of 40% with percentages representing the frequency of how much of a signal is present at a given time. Consequently, the Examiner maintains the 35 USC § 102(e) rejection being anticipated by Struble, U.S. Patent 7,058,443 as set forth in said Office Action and re-submitted herein below.

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2. Additionally, in view of the foregoing argument in support of the 35 USC § 102(e) rejection, Examiner maintains the 35 USC § 103(a) rejection as being unpatentable over Struble and in view of Limousin et al., U.S. Patent 5,584,867 as set forth in said Office Action because claim 1 is not an allowable independent claim.

Election/Restrictions

3. Claims 16–20 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 24 April 2006.

Claim Objections

4. Claim 7 is objected to because of the following informalities: There appears to be a typographical error in line 2: the letter “n” should be the word “in” instead. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1–3, 5, 6, 8, and 10–15 are rejected under 35 U.S.C. § 102(e) as being anticipated by Struble, U.S. Patent, 7,058,443.

7. Struble discloses a processor in electrical communication with one or more sensors and that receives signals from one or more sensors (e.g. Fig. 2), wherein a processor is operative to

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evaluate frequencies of left and right atrial signals (e.g. Figs. 12A–12B) and, if one of the left and right signals has a higher frequency, a processor determines the atrium with the higher frequency to be a source of the atrial flutter, wherein a processor is operative to control a pulse generator to initiate delivery of a therapeutic stimulation via a left or right atrial lead to an atrium determined to be a source of atrial flutter (e.g. column 2, lines 50–65; column 15, lines 49–51, 56–58 (emphasis on in a similar fashion), and 64–67; column 16, lines 1–3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struble as applied to claims 1, 6 and 8 above, and in view of Limousin et al., U.S. Patent 5,584,867.

11. Struble discloses the essential features of the claimed invention as described above except for a threshold provided by a processor comprises flutter events of one atrium depolarization

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preceding a flutter event of the other atrium depolarization in a current cycle by an amount less than 40 percent of an interval between flutter events in one or more preceding cycles (claim 7).

However, Limousin et al. disclose a threshold comprises flutter events of one atrium depolarization preceding a flutter event of the other atrium depolarization in a current cycle (e.g. column 3, lines 9–16; column 6, lines 57–64) to provide appropriate discrimination allowing the pacemaker to avoid confusing a wave doublet from the same atrial depolarization wave front with consecutive atrial depolarization signals. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Struble to include a threshold comprises flutter events of one atrium depolarization preceding a flutter event of the other atrium depolarization in a current cycle, as taught by Limousin et al. to provide appropriate discrimination allowing the pacemaker to avoid confusing a wave doublet from the same atrial depolarization wave front with consecutive atrial depolarization signals.

Limousin et al. do not disclose in a current cycle by an amount less than 40 percent of an interval between flutter events in one or more preceding cycles. However, it would have been an obvious matter of engineering design choice to a person having ordinary skill in the art at the time the invention was made to modify Struble and Limousin et al. to include a current cycle by an amount less than 40 percent of an interval between flutter events in one or more preceding cycles, since it is held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA) 1980). (See MPEP 2144.05) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Struble and Limousin et al. to include a threshold comprises flutter events of one atrium depolarization preceding the

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flutter event of the other atrium depolarization in a current cycle by an amount less than 40 percent of an interval between flutter events in one or more preceding cycles to ensure optimum and accurate performance of the therapy device.

12. Struble discloses a therapeutic stimulation comprises a plurality of stimulation parameters including an amplitude, pulse width, interpulse interval, and number of pulses applied because a stimulation signal is inherently made up of a plurality of stimulation parameters including an amplitude, pulse width, interpulse interval, and number of pulses applied all of which characterize a heart's signals, but is not obvious that at least one of the stimulation parameters is programmable (claim 9). Limousin et al., however, disclose at least one of the stimulation parameters is programmable (e.g. Fig. 1; column 6, lines 12–14) to provide an improved process allowing the pacemaker to avoid confusing therapeutic stimulation when applying appropriate therapy for cardiac management. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Struble to include at least one of the stimulation parameters is programmable, as taught by Limousin to provide an improved process to ensure optimum and accurate performance of the therapy device.

13. Regarding claim 4, Struble discloses the essential features of the claimed invention as describe above except for a processor determines frequencies of left and right atrial signals as the inverse of the interval between detected left and right atrial depolarizations. However, it is well known in the art to use heart rate (inverse of the interval) instead of interval/cycle length, since they are functional equivalents that both equally indicate the condition of the heart. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Struble to include a processor determines frequencies of left and

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right atrial signals as the inverse of the interval between detected left and right atrial depolarizations to correctly indicate the condition of the heart.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this Final Action.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TLS

February 26, 2007

26 February 2007



GEORGE R. SWANNICK
PRIMARY EXAMINER

2/26/7